EDA-GCP Public Inspection Report (PIR) of Clinical Trial Site

Part 1	**General Information**
Clinical medical research site details	
CT site information	
Name of CT site	National Cancer Institute "Site: 3001"
Address of inspected CT site	El Kasr Al Aini street, Cairo
Inspection details	
Dates of inspection	05 September 2024
Type of inspection	Routine
Introduction	
General information about the sponsor and CT site	- The inspected site is a Clinical Trial Site (**National Cancer Institute**) that conducts clinical studies for the sponsor (**Janssen Research & Development, LLC**). - PI name: **Prof. Dr. Mohamed Samra** - Activities include participant recruitment, clinical conduct, sample collection, safety monitoring, and data documentation.
Brief report on inspection activities undertaken	
Scope and limitations	
Areas inspected	- Clinical operations (screening, dosing, follow-up) - Informed Consent Process - Investigational Medicinal Product (IMP) management - Pharmacy / IMP storage area - Bioanalytical / laboratory facilities (if applicable) - Source documents and Case Report Forms (CRFs) - Archiving and documentation system - Quality management system
Out of scope	Not defined
Inspected Clinical medical research	The inspection focused on the following study: - Study Title: Efficacy and Safety of M281 in Adults with Warm Autoimmune Hemolytic Anemia: A Multicenter, Randomized, Double-blind, Placebo-controlled Study with a long-term Open-label Extension - Protocol Number: MOM-M281-0006 -Phase: II/III - EDA initial approval date: 19/07/2023
Type of IMP	Biological Monoclonal antibody (Nipocalimab)

Part 2	
1. Facilities and equipment system	
1.1. Facilities and Trial Conduct	- The site facilities were generally adequate for trial conduct. - Equipment maintenance, calibration, and emergency preparedness were in place. - Dedicated consenting/examination and procedure rooms were available for study-related activities. - Study files were stored in a secure, access-controlled, fire- and water-resistant cabinet. - A dedicated investigational medicinal product (IMP) storage room was available, and the IMP storage conditions were maintained in accordance with the Pharmacy Manual. - Equipment used during the conduct of the clinical trial, including the weight scale, sphygmomanometer, centrifuge, and other relevant study equipment, was reviewed together with the associated calibration documentation and verified for adequacy and compliance with the approved protocol, Good Clinical Practice (GCP), and applicable regulatory requirements. - One observation was identified in accordance with ICH-E6R2 regarding equipment calibration documentation as the weight scale did not have a serial number or calibration label, the sphygmomanometer lacked a calibration label, and the centrifuge calibration label did not indicate the validity period. The sponsor and site addressed the raised observation through corrective and preventive actions, including updating calibration labels, reinforcing equipment verification during monitoring visits, retraining study personnel, and implementing routine verification to ensure calibration labels remain complete and affixed to the relevant equipment.
1.2. Computerized system	- Electronic data capture, as eCRF and randomization systems were in use.
2. Pharmaceutical Quality System	
2.1. Quality Management System	- The Quality Management System was supported by Standard Operating Procedures (SOPs) governing clinical trial conduct, documentation, safety reporting, IMP management, and other quality-related processes. The system was designed to support compliance with the approved protocol, GCP, applicable regulatory requirements, and the protection of participant rights, safety, and data integrity. - The study had been monitored according to the monitoring plan.
2.2. SOPs and Documentation	- The site-maintained SOPs governing clinical trial activities. The applicable SOPs were reviewed during the inspection to assess document control, periodic review, and implementation.

2.3. Deviation Management	- Protocol deviations were handled according to SOPs and were documented in progress reports submitted to EDA. - The procedures and documentation related to the identification, reporting, assessment, and management of protocol deviations, including associated investigations and corrective and preventive actions (CAPA) reviewed and insured compliance with GCP.
2.4. CAPA System	- A CAPA system was established at the site. A Comprehensive CAPA responses addressing all findings and recommendations were prepared and submitted within defined timeline - All corrective actions were implemented and supported with documentation as proof of correction in compliance with applicable GCP and regulatory standards.
3. Ethics and participant Protection	
3.1.Informed Consent Process	- The informed consent process was assessed through the review of the approved ICFs, participant source records, informed consent documentation, and other relevant essential trial documents to verify compliance with the approved protocol, GCP, and applicable regulatory requirements. - Approved Informed Consent Forms (ICFs) were available and used as follows: • ICF for adult(s): Version 2.1 (dated: 01/02/2024) • ICF for pregnant participant or pregnant partner: Version 1 (dated: 03/11/2022) - All informed consents were signed by participants prior to the performance of any study-related procedures, in full compliance with GCP guidelines. The procedure for obtaining informed consent from participants was confirmed to be fully in line with the requirements of GCP guidelines.
3.2. Ethics Committee Approval	- All approvals were confirmed to be available, current, and filed appropriately in the site master file. • **IRB Approval** on: 28/03/2023 • **MOH approval** on: 31/05/2023
3.3. Participant Safety	- Participant safety was assessed during the inspection through the review of participant source records and other essential clinical trial documentation, together with verification of clinical trial facilities relevant to participant care, including patient procedure and assessment areas, the MP management process, pharmacy, laboratory facilities, and other key trial areas, as applicable.

	- The inspection activities were performed and verified that the conduct of the clinical trial supported the protection of study participants in accordance with the approved protocol, GCP, and applicable regulatory requirements.
4. Personnel and Training	
4.1. Training and qualifications	- Roles and responsibilities of study personnel were clearly defined. - GCP training records were available and reviewed. - The qualifications and training of the investigator and study personnel were reviewed during the inspection and verified that delegated trial-related responsibilities were supported by appropriate qualifications and documented delegation records by a review of curriculum vitae (CVs), delegation of responsibilities records, protocol-specific training documentation, and other relevant personnel qualification records, as applicable. - One observation was identified regarding the delegation of trial-related responsibilities, where a Sub-Investigator was delegated study responsibilities before notification to the EDA **in accordance with CT law 214/2020 and its executive regulation 927/2022, and the Guideline for Good Regulatory Oversight of Clinical Trials by Egyptian Drug Authority.** The sponsor implemented corrective and preventive actions, including submission of the required notification, issuance of a global reminder to relevant personnel, and regulatory training for the study team, The submitted CAPA was reviewed and accepted by EDA.
5. Investigational Product (IMP) Management	
5.1. IMP handling	- Shipping records detailing the quantity and the batch numbers of the IMPs received at the site were available. - Printout of the data logger of temperature during transportation of IMP from the depot to the clinical trial site was verified. - Dispensing records were verified during the inspection. - IMP accountability, including receipt, dispensing, return, reconciliation, and traceability, was verified.
6. Clinical Trial Conduct	
6.1. Protocol Compliance	- Approved Signed protocol (Version: Amendment 6.0, dated: 18/08/2022) was confirmed to be implemented at the site. - participant source records, case report forms (eCRFs), and other relevant essential clinical trial documentation was verified the compliance with the approved protocol, GCP, and applicable regulatory requirements. - One observation related to protocol implementation and regulatory requirements were identified during the inspection as a local laboratory was

	used before submission of the required documentation to the EDA **with compliance with CT law 214/2020 and its executive regulation 927/2022, and-the Guideline for Good Regulatory Oversight of Clinical Trials by Egyptian Drug Authority.** In response, the sponsor implemented corrective and preventive actions, including submission of the required regulatory documentation, regulatory training for the study team, and reinforcement of procedures to ensure timely regulatory notification. The submitted CAPA was reviewed and accepted by EDA.
6.2. Source Data and CRFs	- Source documents and case report forms (eCRFs) were reviewed during the inspection and verified the completeness, accuracy, consistency, and traceability of clinical trial data in accordance with the approved protocol, GCP, and applicable regulatory requirements. - The inspection included a comparison of participant source records with the corresponding study documentation, as applicable. - Two documentation-related observations were identified during the inspection in accordance with ICHE6R2. For one participant, the FACIT questionnaire completed at one of the visits was not dated. In addition, a site staff member assigned the role of administrator in the delegation log documented and signed information in the participant source records despite not being delegated to perform that trial-related activity. The sponsor implemented corrective and preventive actions, including retraining of the study coordinator on documentation requirements, reinforcement of delegated responsibilities, and additional regulatory training. The submitted CAPA was reviewed and accepted by EDA.
6.3. Delegation of Duties	- The delegation of trial-related responsibilities was assessed during the inspection through the review of the Site Signature and Delegation of Responsibilities Log and other relevant study documentation to verify that trial-related duties were appropriately assigned to qualified study personnel in accordance with the approved protocol, GCP, and applicable regulatory requirements.
7. Laboratory and Bioanalytical Activities (if applicable)	
- An External Central and Local laboratory were used for bio-samples analysis. - Laboratory and bioanalytical activities were assessed during the inspection through the review of laboratory-related documentation and a visit to the laboratory facilities involved in the clinical trial, as applicable, and verified the compliance with the approved protocol, GCP, and applicable regulatory requirements.	
8. Safety Reporting (SAE)	

- SOPs for SAE reporting was available.
- Safety reporting was assessed during the inspection through the review of AEs and (SAEs) documentation and other safety-related records, as applicable, and verified the compliance with the approved protocol, GCP, and applicable regulatory requirements.

Part 3	**Inspection outcome**
Based on the reviewed documentation, inspected facilities, and observations identified during the inspection: The clinical trial site was considered to be operating at an acceptable level of compliance with GCP guidelines and applicable regulatory requirements as all identified deficiencies were communicated to the site and the CAPA were implemented to address the observations. This EDA-GCP-PIR remained valid until the next inspection, provided no critical findings, safety concerns, or regulatory actions arise.	

Part 4	**List of national Laws and GCP Guidelines referenced in the inspection report**
1. Law of Regulating Clinical Medical Research no.214/2020. 2. Prime Minister's Decree No. 927 of 2022 On Promulgating the Executive Regulation of Law on Regulating Clinical Medical Research Promulgated by Law No. 214 of 2020 3. EDA Chairman Decree No.111 for 2022. 4. Guideline for Good Regulatory Oversight of Clinical Trials by Egyptian Drug Authority "EDREX.GL.Bioinn.006". 5. Guideline for Good Clinical Practice ICH E6r2. 6. Declaration of Helsinki 7. WHO Handbook for Good Clinical Research Practice (GCP) -Guidance for Implementation	

Abbreviation	
AE	Adverse Event
CAPA	Corrective and Preventive Action
CRF	Case Report Form
CRC	Clinical Research Center
CT	Clinical Trial
CV	Curriculum Vitae
EDA	Egyptian Drug Authority
FACIT	Functional Assessment of Chronic Illness Therapy
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Conference of Harmonization
IMP	Investigational Medicinal Product
IRB/IEC	Institutional Review Board / Ethics Committee
MOH	Ministry of Health
PI	Principal Investigator

PIR	Public Inspection Report
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
WHO	World Health Organization

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